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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,606	09/15/2003	Joseph Kanner	25629	9306

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,606

Applicant(s)

KANNER ET AL.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-260 is/are pending in the application.
- 4a) Of the above claim(s) 1-94 and 123-260 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 95-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicant's election without traverse of Group VII, claims 95-122, in the reply filed on 10/17/05 is acknowledged. Please inform the examiner as to how this application differs from parent case 09/915,527 in order to properly select the priority date. No foreign search report is found in this file.

It appears the point of novelty may reside in extracting carotenoids with both an esterase and an emulsifier in some fashion. No novelty is seen in the claimed emulsifiers or source of carotenoids. And employing "recycled" reagents is given no patentable weight.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 95, 96, 98, 100-101, 103, 109-111, 120 are rejected under 35

U.S.C. 102(a) as being anticipated by Breithaupt.

Breithaupt (Z Naturforsch) entitled "Enzymatic Hydrolysis of Carotenoid Fatty acid Esters of Red Pepper by a Lipase from *Candida ruguosa*" teaches in the abstract, red pepper extracts treated with lipase to obtain free carotenoids. On page 972 column 2, lipase catalyzed ester hydrolysis is described where the samples were extracted with ethyl acetate, combined with buffer, bile salts, and CaCl_2 , then lipase with CaCl_2 were

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added and incubated. On page 973 column 1, the suitability of the enzyme was estimated for hydrolyzing the extracts.

All of the claimed features are taught by Breithaupt for the same function as claimed.

Claims 97, 99, 104-107, 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breithaupt.

Breithaupt (Z Naturforsch) entitled "Enzymatic Hydrolysis of Carotenoid Fatty acid Esters of Red Pepper by a Lipase from *Candida rugosa*" teaches in the abstract, red pepper extracts treated with lipase to obtain free carotenoids. On page 972 column 2, lipase catalyzed ester hydrolysis is described where the samples were combined with buffer, bile salts, and CaCl_2 , then lipase with CaCl_2 were added and incubated. On page 973 column 1, the suitability of the enzyme was estimated for hydrolyzing the extracts.

The claims differ from Breithaupt in that claim 97 is directed to the emulsifier being lecithin specifically and in claim 99 to a non-ionic detergent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select any desired emulsifier in view of Breithaupt who teaches bile salts because one would have a high expectation of success to employ any known emulsifier for its known function with the expected result in the method of Breithaupt. No unexpected results are seen in the claimed selections of emulsifiers.

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Claims 104-107 differ from Breithaupt in that they specify the source of the carotenoids is red pepper powder, paprika or red pepper oil extract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select any form of red pepper in view of the teachings of Breithaupt who teaches red pepper fruit specifically which is extracted because each of the claimed red pepper related products/extracts are colored red and would be expected to contain carotenoids. Note that paprika is red pepper in Hungarian.

Claims 121-122 are directed to pH conditions of the extraction which are not specifically taught by Breithaupt.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select any desired pH for the extraction taught by Breithaupt because selecting pH to optimize efficiency of a known method for its art recognized function is well within the purview of the practicing artisan absent a showing otherwise and obtainable by routine experimentation which is within the skill of one of ordinary skill in this art. No criticality is seen in the selected pH ranges.

Claims 112-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Breithaupt in view of Kiy.

The claims differ from Breithaupt in that they specify the lipase is immobilized.

Kiy (6,350,890) entitled "Method for Obtaining Fatty Acids from Biomass by Combined In Situ Extraction, Reaction and Chromatography Using Compressed Gases" teaches in column 2, immobilized lipases for performing enzymatic reactions. In column 15 Example 16 teaches carotenoids are found in algae and may be extracted.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an immobilized lipase as taught by Kiy in the method of Breithaupt because such is well known in industrial process utilizing enzymes and would have the expected result in the presently claimed invention. Kiy teaches industrial processes employing immobilized lipase to extract substances and one would expect immobilized lipase would function as least as well as free lipase in the method of Breithaupt.

Claims 102, 114-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Breithaupt in view of Kanner.

The claims differ from Breithaupt in that claims 114-119 include additional enzymes to the lipase taught by Breithaupt. And claim 108 includes oranges as a source of carotenoids.

Kanner (Int Fruchtsaft Union) entitled "Carotenoids Extraction From Orange Peel by Treatments With Enzymes and D-Limonene" teaches in the abstract, treating plant parts to extract carotenoids with pectinases and cellulases. On page 223 carotenoids were solubilized in water by mixing with Tween-80.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the pectinases and cellulases of Kanner in the method of Breithaupt because Kanner extracts carotenoids from plant materials and the enzymes are employed to assist in the efficient extraction. Once the carotenoids are extracted, the method of Breithaupt then separately produces free carotenoids from the extract

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obtained. Breithaupt extracts carotenoids from plant materials with standard solvents. To employ one known extraction method, such as that taught by Kanner, and then to employ a known method to produce free carotenoids such as taught by Breithaupt, would have been obvious because they would have the expected result. The two methods are independent where the method of Breithaupt would work with carotenoids extracted by any method.

Further, Kanner teaches carotenoids extracted from orange peel.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 118 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 118, "proteins" lacks antecedent basis and the members of the group are inconsistently singular and plural. Please review the spelling and punctuation in claim 108.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zorn (US 2004/0147005 A1) teaches carotene specific lipases.

Mehta (6,200,597 B1) teaches carotenoid formulations.

Lueddecke (4,844,934) teaches carotenoid formulations.

Bodor (US 2003/0017239 A1) teaches carotenoid compositions.

Bridges (US 2003/0054070 A1) extracting carotenoids.

Khachick (Anal Chem) entitled "Identification, Quantification, and Relative Concentrations of Carotenoids and Their Metabolites in Human Milk and Serum" teaches on page 1874 column 1 last paragraph bridging to column 2, extracting carotenoids from milk with sodium cholate and sodium deoxycholate, $MgCO_3$, and pronase E.

Fernandez (J of Food Composition and Analysis) teaches extracting carotenoids with enzymes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
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